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Current severe psoriasis and the Rule of Tens

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Summary

This review addresses the problems of defining severity of psoriasis. Concepts of severity depend on the timescale perspective from which judgement is made. Measurement needs to include assessment of signs, impact on the patient's life and the history of the disease. The concept of severity in relationship to quality of life measurement scores has been defined, so it is now possible to postulate a standard, easily remembered concept to help define 'severe psoriasis' in the clinic. The proposed Rule of Tens for current severe psoriasis from the clinician's viewpoint is: 'Current Severe Psoriasis = Body Surface Area involved > 10% or Psoriasis Area and Severity Index score > 10 or Dermatology Life Quality Index score > 10'.

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The author is joint copyright owner of the DLQI and PDI and his department gains some income from the use of the DLQI in research studies.

Although every dermatologist instinctively understands the concept, defining severe psoriasis is fraught with problems. There are many reasons for this. The concept of severity depends on the differing perspectives and interests of the assessor. Current severity is different from long-term severity. Comparative severity in an individual is different from absolute severity in a population, and the factors that contribute to severity are conceptually separate and may be contradictory. This article aims to clarify these reasons, reviews different approaches to defining severity and proposes a very simple concept to be of practical daily use to busy clinicians. The importance of attempting to measure psoriasis severity in a meaningful, relevant and practical way has been addressed by several authors[1–6] over the last 35 years. This review draws on their experience and concepts.

Every dermatologist is familiar with the extraordinary breadth of reactions of people with psoriasis to their disease. Someone with a few very small plaques may be devastated by their disease, especially if visible, whereas another patient with 50% body surface involvement may be apparently undisturbed and lead a normal life. Clinicians may need assistance in perceiving the severity of psoriasis from the patient's point of view.[7] Many patients feel that their treatment is not aggressive enough,[8] particularly if the clinician fails to understand or to acknowledge the impact of psoriasis on individual patients.[9]

Reaching a common terminology of how to define severity is particularly important in research, in clinical practice and for audit to evaluate the extensive range of new therapies becoming available for the treatment of 'severe' psoriasis. In healthcare systems reliant on 'gatekeepers' to access specialist dermatology care, appropriate criteria for referral are needed. As litigation culture strengthens and as healthcare organizations seek to contain costs, clinicians increasingly need to be able to justify their clinical decisions and to provide evidence of why their clinical decisions were appropriate if later challenged. In planning healthcare expenditure, it is necessary to be able to estimate likely drug usage and that can only be done if concepts of disease severity and treatment indications are defined.

The difficulties inherent in defining psoriasis severity were emphasized at a recent Consensus Conference on biological therapies in the systemic management of psoriasis.[10] In this context moderate to severe psoriasis was understood to be a disease for which systemic therapy was appropriate: in view of the complexity of the issues in its definition, the authors stated that disease severity definition is considered on a case-by-case basis.

Severe to whom?

The factors contributing to the concept of psoriasis severity differ depending on the perception of the assessor. Patients,

employers, clinicians, clinical researchers, healthcare organizations and regulatory authorities such as the U.S. Food and Drug Administration (FDA) will all emphasize different aspects. From the patient's perspective, psoriasis will be considered severe if it causes embarrassment or anxiety, pruritus or soreness, if it affects relationships, everyday activities, work, studying or sport, or if there is joint involvement. A survey of 600 patients with psoriasis[11] concluded that psoriasis causes a substantial burden even when not extensive and is associated with widespread treatment dissatisfaction.

From an employer's perspective, psoriasis is severe if it impacts on an employee's ability to work, causes time off work or has an adverse effect on other employees or customers. From a dermatologist's point of view, psoriasis is severe if it is very widespread, if the patient appears very concerned, if the patient is erythrodermic or widely pustular or if there are special presentations such as scalp, flexural or acral involvement. Severity is also suggested by poor response to therapies, especially over the long term or requiring inpatient or intensive treatment.

From the clinical researcher's traditional viewpoint in assessing the effectiveness of treatment, severity may focus on clinical signs such as area of involvement, degree of scaliness, redness and thickness. Administrators and those who allocate resources or reimbursement in healthcare organizations such as the National Health Service may focus their concept of severity on those patients who are high users of resources. Patients admitted to hospital, using expensive therapy, needing frequent visits to hospital and who have long-term chronic disease may all be considered to have severe disease from this perspective.

Current and long-term severity

As psoriasis is a fluctuating and unpredictable disease, the time period over which severity is measured will have a major influence on its assessment. In daily decision taking in the outpatient clinic, what primarily matters is current severity or severity 'now', although the long-term history informs the understanding of the patient's needs. However, for assessment of 'long-term' severity, or overall classification of patients, long-term history of the disease including number of flares, years since disease started, number, duration and efficacy of length of systemic therapies and number of admissions are all relevant. The current disease activity is only part of this long-term overall assessment. Some patients are seen with high long-term severity whose current severity is low, yet other patients present with high current severity despite low long-term severity.

Severity: comparative or absolute?

In daily clinical practice a key question in patient assessment is: How has the psoriasis altered recently, in particular since last reviewed? If it is better, worse or the same a judgement must be made as to whether this is due to recent treatment or to altered underlying disease activity. This concept of 'comparative' 'within-patient' severity does not require reference to other patients. It is generally informally assessed without attempt at measurement, although its assessment could perhaps be enhanced by such attempts. However, for audit, research or planning of resources for patients with psoriasis it is essential to be able to measure 'absolute' severity using agreed criteria. In the concept of 'absolute' severity there are two approaches to fulfil different needs: methods to measure and compare patients with psoriasis with each other and methodology to measure and compare psoriasis patients with patients with other diseases.

Comparing one type of skin disease with another poses practical and philosophical difficulties: these difficulties are much greater when attempting to compare severity of a skin disease with disease of other organs. Politically, dermatology organizations must be able to demonstrate the importance of skin disease in comparison with other diseases in order to influence resource allocation. One approach is to use validated Quality of Life (QoL) indices: measuring the secondary impact of the disease on the patient's life rather than the disease itself. A recent U.K. parliamentary report has recommended that the government should take properly assessed QoL fully into account in all health policy developments.[12] Two studies using the general health-related QoL measures, the SF-36[13] and the Sickness Impact Profile,[14] have demonstrated that people with psoriasis experience equivalent or greater impact on QoL compared with people with cardiac or respiratory disease. Using similar concepts of dermatology-specific QoL measures to compare across different skin diseases, widespread use of the Dermatology Life Quality Index (DLQI) has demonstrated that psoriasis and eczema have a greater impact on QoL than most other skin diseases.[15]

The Dermatology Index of Disease Severity was proposed as an attempt to define different severities across a range of skin disease.[16] In this classification, severe disease was defined as the presence of erythroderma with $>90\%$ body surface involvement and/or hand, foot or mucous membrane involvement with severe functional limitation requiring external assistance. When tested in a group of patients with psoriasis the concept showed good interobserver concordance across a range of psoriasis severities.[16]

Definition of severity

Definition of psoriasis severity may encompass subjective or objective assessment of physical aspects of disease, symptoms, measurement of the impact of the disease on the patient and classification of the long-term history of the disease and its response to therapy. A recent review of psoriasis severity measures[5] identified use of the following techniques: Body Surface Area (BSA) involved, Psoriasis Area and Severity Index (PASI)[17] and Self-Administered PASI (SAPASI),[18] Physician's Global Assessment, DLQI,[19] National Psoriasis Foundation score,[5] the Salford Psoriasis Index (SPI),[20] the Lattice System Physician's Global Assessment (LS-PGA)[21] and the Psoriasis Symptom Assessment (PSA) scale.[22]

Body Surface Area estimation: one handprint = 1%

If percentage of BSA involved is to be used as one possible indicator of psoriasis severity, it is important that the assumptions on which measurement techniques are based should be accurate. However, it is often erroneously suggested or implied that the surface of 'the palm' is approximately equivalent to 1% of the total BSA.[23] Unfortunately it is often not clear whether 'the palm' refers only to the actual palm or whether this refers to the full palmar aspect of the hand including the fingers and thumb. We demonstrated that the surface area of one side of the full outstretched hand, including the five digits, is approximately equivalent to 0·8% (males) or 0·7% (females) of the BSA.[24] This has since been confirmed both in adults[25] and in children (0·94% in children).[26] Use of the incorrect assumption that the area of the localized palm surface alone is equivalent to 1% BSA could lead to a 50% overestimation of BSA involvement. It is suggested that, for the purpose of approximate clinical estimation, the total palmar surface of palm plus five digits be assumed to be approximately equivalent to 1% (remembering that in fact it is slightly less than 1%). This area could be thought of as a 'handprint', analogous to a 'footprint'.

To be fully accurate it is the patient's hand that should be used as the measuring device. In practice this concept already includes several approximations and the use of the physician's hand is unlikely to make a substantial difference to the estimation. Measurement of total area of involvement by the clinician is aided by imagining if scattered plaques were moved so that they were next to each other and then estimating the total area involved.

Physical severity: subjective assessment and Psoriasis Area and Severity Index problems

Contrary to current apparent assumptions, the PASI is not the only way to record psoriasis signs subjectively. Seven years after its description in 1978[17] it was only used as the assessment method in three of 30 psoriasis studies published.[27] Basic flaws of the PASI concept have become clear: its adoption with no attempt at validation for test–retest or intraobserver reliability, its dependence on area assessment at which clinicians are notoriously inaccurate, its lack of clear definition of desquamation and infiltration (although erythema is defined), and its nonlinear, inaccurate and clumsy mathematics.[27–30] It is evident that the PASI concept is too clumsy to use in busy daily routine clinics: indeed it was not designed for use in this setting.

The PASI system, however, has two major advantages: it is sensitive to change and so score change does reflect disease improvement or worsening. Its widespread use in the research setting means that it is now at least theoretically possible to compare information from different studies, in contrast to the incompatibility of measures used up to the 1980s. Presumably these were the influences behind the adoption of the PASI by regulatory authorities as the preferred measurement tool, despite its flaws. Ideally, psoriasis severity should be assessed by validated methodology which reflects the clinical reality of the disease and its management.

In the PASI system, the head, trunk, upper extremities and lower extremities are assessed separately. In each of the four areas erythema, infiltration and desquamation are assigned a score from 0 to 4. For each area an estimate is made of the percentage area involvement and this percentage is converted in a nonlinear fashion to a score from 0 to 6. The scores are then entered into a formula which depends on the approximately correct assumption that the head = 10%, upper extremities = 20%, trunk = 30% and lower extremities = 40%. The authors made a mistake in describing this area allocation in the very first paragraph of the original description[17] of the PASI, resulting unfortunately in repetition of the error in some later publications.[31] Efforts have been made to redefine the area assessment in PASI[32] and to create similar but simpler concepts.[33]

It is important to recognize that in an individual patient the PASI score does not predict the impact of psoriasis on QoL, but 'patient-reported severity' does correlate with other QoL measures.[34] Site of involvement and patient personality and attitudes are critical influences. It is the poor correlation between PASI and QoL measures that argues for their measurement in parallel.

Regulatory authorities such as the FDA increasingly use a change in PASI score to evaluate new therapies for psoriasis. The number of patients who experience 75% improvement from baseline in their PASI score on treatment is used to compare different therapies. The patient population experiencing a 50% improvement in their PASI score could also be considered a clinically significant endpoint,[35] as the PASI score is nonlinear, effective therapy can be differentiated from placebo at this endpoint and DLQI scores are usually improved when this point is reached. Patients who relapse do not reinstigate their own treatment until their disease has worsened back to 20% below their baseline score.[35]

The levels at which PASI scores represent severe psoriasis were considered even in its original publication, which stated that 'under normal circumstances a patient with a PASI score above 10 would be considered for hospitalization with our present treatment policy'.[17] Feldman has explained the consequences of changes in the different sign scores on the final PASI score,[6] and argued that for clinical trial criteria there should be at least 10% BSA involved and a PASI of >11; in clinical practice, when systemic treatment is being considered, there should be 5–10% BSA involvement, or disabling disease or significantly reduced QoL.

Quantitative evaluation

The PASI and other similar techniques all depend on subjective assessment by an observer. Developments in objective quantitative evaluation in psoriasis, including ultrasound, corneometry, laser Doppler velocimetry, transepidermal water loss and

the use of stereoimage optical topometry have been reviewed.[36] There are techniques to measure redness, thickness, scaling and area, although at present these are not widely used in the clinical or research trial settings.

Objective measurement of psoriasis is clearly desirable, and it would be disappointing if in the future objective methods of assessing psoriasis severity were not adopted widely. However, for any objective technique of clinical measurement to be widely adopted it needs to be validated, demonstrating reliability and repeatability, to have identified 'expected' or 'normal' ranges and to have the ability to reflect the overall disease state. In addition, it ideally should require little training, preferably be relatively inexpensive and have demonstrable advantages over simpler subjective clinical methods. At present none of the methods available fulfils all of these criteria. Perversely, once a measurement technique becomes widely adopted, whatever its merits or disadvantages, the published experience of its widespread use answers some of the validation questions and in turn encourages further use. None of the present objective methods has yet reached this critical take-off point of acceptance, although the experience of the use of ultrasound to measure plaque thickness is encouraging.[37]

The histological findings in psoriasis reflect the stage of the evolution of the area biopsied and the overall severity of the disease process. For example, severe pustular psoriasis will demonstrate a massive epidermal infiltrate of polymorphs. There is no body of published work to suggest that knowledge of histological findings in patients with psoriasis will influence management decisions. In routine clinical practice it is impractical and probably unethical to contemplate frequent biopsies to determine the stage or severity of the disease.

Symptoms

Several frequently used measures, such as BSA involvement, PASI and SAPASI, do not assess patient symptoms. The prevalence of symptoms experienced by patients with psoriasis is high, and the importance of including symptoms in the evaluation of disease severity has been stressed.[38] The DLQI does include one question relating to symptoms and the Skindex includes symptom questions. The PSA scale (derived from Skindex) specifically addresses symptom levels.[22] Symptoms do lead to QoL impairment and so assessment of QoL will partially reflect symptom level.

Severity and quality of life

A recent review addressing the definition of mild, moderate and severe psoriasis[4] concluded that BSA involvement alone inadequately measured severity, and that a QoL standard would be a better way to define severe psoriasis. This view was confirmed by a study which revealed no relationship between QoL and overall area involvement, although there was a significant correlation between QoL and the involvement of visible sites.[39] Two further studies[40,41] assessed the correlation between scores from a series of physical signs measures and from QoL measures. Both studies demonstrated that the scores fell into two clear and separate clusters of signs and of QoL measures, providing further evidence to support the use of both types of measure.[41]

In the 'QoL-based definition' of severe psoriasis, as suggested by Krueger *et al.*,[4] one of the defining features was that the disease alters the patient's QoL. However, the extent to which QoL would be expected to be altered was not defined. QoL can be measured in several ways in patients with psoriasis.[42] These include psoriasis-specific measures such as the Psoriasis Disability Index (PDI),[43] PSORIQoL or the Psoriasis Life Stress Inventory,[44] dermatology-specific measures such as the DLQI or Skindex[45] or general health measures such as the SF-36[46] or EuroQol-5.[47]

The PDI was the first psoriasis-specific QoL measure[43] and has been widely used since its early origin, in at least 57 studies in 20 countries and in 13 languages.[48] There is widespread experience of the use of the PDI and evidence of the sensitivity of the PDI to change, and so scores can be interpreted based on this experience.[48] Specific data relating to the least change in the score that is of importance to patients have not yet been prospectively identified. This body of experience, however, indicates that a mean PDI of 49% is seen when patients are admitted for treatment, 51% when starting ciclosporin and 28–40% when starting ultraviolet therapy.

PSORIQoL, a psoriasis-specific measure of QoL, is a recently introduced 25-item instrument which may also be of value in clinical practice and trials.[49] Another psoriasis-specific QoL measure, the Psoriasis Quality of Life Questionnaire, has been used to identify physician- and patient-rated severity levels in psoriasis. A mean score of 7·6 was associated with patient-rated severe psoriasis.[50]

The DLQI is a QoL measure that can be used across all skin diseases. There is now very widespread experience of its use in over 36 diseases in at least 130 studies in 17 countries and 21 languages.[15] It has been used in over 35 studies in psoriasis, and in particular has been used very extensively over the last 3 years in the assessment of the new generation of systemic therapies for psoriasis.[51] The DLQI was able to detect changes in SAPASI and, equally importantly, was able to detect small significant changes over time.[52] The DLQI and PASI measure different aspects of psoriasis, and it has been shown that the informative value of clinical research in psoriasis is improved by the inclusion of the DLQI.[53] There are extensive published data giving typical mean values of the DLQI in patients with psoriasis associated with different clinical decisions.[15] For example, mean DLQI was 14 at admission to hospital,[54] 13 at start of phototherapy,[55] 10, 12 and 15 on starting systemic therapy[55–57] and 4 on discharge from outpatients.[55]

The problem with all 'new' scoring systems is that they are of little or no use in the clinical setting if the clinician is not able to interpret the absolute meaning of a score or a change in score. A pilot study of the DLQI showed that a score change of ± 4 was the change that would be meaningful or

matter to a patient.[58] The meaning of absolute score has been clarified by a recent study[59] in which 1993 patients completed the DLQI and a global question. Based on this, the following DLQI score banding has been proposed: 0–1 means 'no effect on QoL'; 2–5, 'small effect'; 6–10, 'moderate effect'; 11–20, 'very large effect'; 21–30, 'extremely large effect'. These bands are relatively easy to remember. Perhaps the most critical single concept to arise is that if the DLQI is greater than 10, this represents a skin disease having a very large effect on a patient's life, meriting intervention. This information concerning the DLQI allows it potentially to provide clinically useful data in assisting management of patients with psoriasis, for example where systemic therapy is being considered or used.

In a consensus statement on psoriasis therapies the American Academy of Dermatology concluded: 'treatment decisions should include QoL considerations in selecting optimal therapy'.[60] It is now at least possible to understand scores of the DLQI in this setting. However, very little is known about the current relationship between clinical decision making in psoriasis and QoL scores. In 199 psoriasis patients in whom there was no change in therapy at outpatient consultation, 36% had DLQI scores greater than 10.[55] There may be good reasons why treatment was unchanged in these patients, but it is likely that at least in some of these patients, more aggressive therapy was indicated: knowledge of QoL scores may have resulted in more appropriate treatment.

In a clinical trial, the concept of a 75% or 50% change in DLQI could be used to assess efficacy of treatment. However, what is important from the viewpoint of patients is that their QoL is improved to a level that is either unaffected (DLQI score 0–1) or to a level at which the disease has only a 'small effect' on QoL (DLQI score 2–5). A goal for an individual is therefore to improve the QoL so that a DLQI of 5 or less is reached.

Utility questions are another technique to gain insight into the attitudes and extent of concerns of patients towards their skin disease. These questions pose hypothetical choices, such as: 'if there were a simple permanent cure for your psoriasis, how much would you be prepared to pay for the cure?'[61] Thirty-eight per cent of patients were prepared to pay £10 000 or more, suggesting that from these patients' viewpoint, their psoriasis was severe. Such 'willingness to pay' questions correlated with PDI scores.[62] Further insights can be gained by using 'standard gamble' and 'time trade-off' questions, as have been applied to methotrexate treatment decisions.[63]

Proposed solutions

The concept of 'psoriasis severity' includes components that cannot be meaningfully merged into a single score. Long-term severity and current severity, clinical signs, QoL score and history cannot and should not be amalgamated in a single score. The SPI addresses this by giving three separate scores representing signs, psychosocial disability and intervention.[20] This is a philosophically sound approach and this index is likely to be useful for staging patients for the purposes of clinical studies. The signs score is calculated by converting the PASI score to a 1–10 score in a nonlinear fashion. The SPI triple score can be used to gain insight into the severity of a patient's psoriasis and into the likely difficulty of management. In contrast, the National Psoriasis Foundation psoriasis score[5] has five separate scores recording induration, area, physician's global assessment, patient's global assessment and itching: it is suggested that these can be combined to a total score.

The LS-PGA has been proposed[21] for use in psoriasis. There was a high correlation between PASI, Psoriasis Global Assessment and LS-PGA and, in addition, LS-PGA had a lower inter-rater variation than PASI. The concept of the LS-PGA is of interest, providing classification descriptors of differing combinations of area and signs. The description of the instructions[21] used to calculate percentage BSA for the LS-PGA appears to differ from that as clarified above.[24,25]

For a clinical trial setting, Feldman suggested[6] that a patient would be defined as having severe psoriasis if either 10% BSA is affected or if PASI >11, although in clinical practice he suggested that >5–10% BSA would indicate candidature for systemic treatment. These concepts were endorsed by the majority of the Medical Board of the National Psoriasis Foundation.[6] Despite these suggestions, Feldman states that psoriasis severity may be better defined by the impact of psoriasis on QoL.

The Rule of Tens

In the busy clinical setting, clinicians need simple, easily remembered and easily applied concepts to aid clinical decision making. Use of the definition of severe psoriasis as BSA involved $>10\%$[6] can be aided by using the concept of the outstretched hand, including fingers and thumb (a 'handprint') being approximately equivalent to 1% BSA.[24] An area of psoriasis totalling more than 10 handprints is clearly severe. The concept of $>10\%$ of BSA being involved was also incorporated as one of the defining characteristics of a 'QoL-based definition of severe disease'.[4]

The concept of a minimum PASI score being equivalent to severe psoriasis would be useful in giving more meaning to the flawed PASI concept. Although Feldman[6] proposed that PASI >11 equated to severe psoriasis, the above analysis of PASI scoring and the original description that a score of >10 is that at which admission might be expected,[17] suggests that it would be reasonable and meaningful to consider a PASI score of >10 as indicative of severe psoriasis.

Recent work[59] has demonstrated that a DLQI score of >10 means that a skin disease is having a very severe effect on the patient's QoL. This finding provides a possible solution to the quandary that there has been wide agreement of the central importance of QoL impairment in defining psoriasis severity, but no previous validated way of meaningfully defining this.

In view of the above, the following simple practical concept to aid clinical decision taking in psoriasis is now proposed: the Rule of Tens, where current severe psoriasis =

BSA involved > 10% (i.e. 10 hand areas) or PASI score > 10 or DLQI score > 10.

Patients who fulfil any one of these three criteria should be considered to have severe psoriasis for which active intervention is likely to be required. A fourth pun may be added: 'or tender painful areas', as this implies disabling or flaring disease. The Rule of Tens is suggested for use by clinicians in evaluating patients in a clinical (not research) setting. It should be noted that the proposed Rule of Tens would not be of relevance in assessing long-term severity of psoriasis or for monitoring purposes.

The concept of the Rule of Tens has arisen from the serendipitous constellation of a critical score of 10 in three different psoriasis measuring methods. The score systems are all essentially arbitrary measuring techniques, although the DLQI score banding is validated. It is hoped that the Rule of Tens may be useful in the clinic and helpful as a simple educational tool to familiarize clinicians with the meaning of various score systems. The impact of this concept now needs to be validated prospectively in a variety of clinical settings.

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